UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,334	12/30/2004	Mitsuru Maeda	47233-0042	8952

55694 7590 08/28/2007

DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,334	MAEDA ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,9,11-15,21 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,11,12,14,15,21,26,27 and 30* is/are rejected.

7)☒ Claim(s) *13,28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 5/25/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 27-30 have been added

Claims 2-710, 16-20, and 22-25 have been canceled.

Remarks drawn to rejections of Office Action mailed 1/19/2007 include:

102(b) rejection: which has been maintained for reasons of record.

103(a) rejection: which has been maintained for reasons of record.

An action on the merits of claims 1, 8-9, 11-15, 21, and 26-30 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The rejection of claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al. (US 5,407,812) is maintained for reasons of record.

Sakai et al. disclose 2-O-β-D-glucopyranosyl-L-ascorbic acid, which meets the limitations of claim 1 of the instant application (see column 3, line 23).

Applicants argue that the structure in column 2 is not the claimed compound, and the examiner agrees with this. However, in column 3, line 23, Sakai et al. disclose the instantly

claimed compound. Applicants argue that the disclosure of the beta form is a typographical error in the Sakai reference, as the patent is drawn to the use of the alpha form of the compound. However, this is not found convincing, as even if the disclosure of the beta form were a typographical error, this would not cure the fact that the beta form of the compound was still disclosed prior to the filing of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 8, 9, 11-12, 14-15, 21, and 26 under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. as applied above, in view of Kawada et al. (US 4,754,026), is maintained for reasons of record. Newly added claims 27 and 30 are rejected herein additionally.

Claim 1 is drawn to a 2-O-β-D-glucopyranosyl-L-ascorbic acid compound. Claims 8 and 9 provide the saccharide comprises acetyl groups in the 2', 3', 4', and 6'-positions of the sugar. Claims 11 and 12 are drawn to methods of making the product using a glucosyltransferase. Claims 14-15, 21, 26-27, and 30 are drawn to various forms of compositions comprising the active agent.

Sakai et al. disclose the non-acetylated compound as set forth supra. Sakai et al. teach to make their compounds using a saccharide-transferring enzyme (see paragraph bridging columns 3 and 4). Sakai et al. teach that an amount of 0.001% or more is acceptable for use of their alpha-derivative (see column 8, lines 33-48). Sakai et al. also teach that their composition may be used in various forms, such as cosmetic, pharmaceutical, or dietary uses (see column 9, lines 49-61). What they do not teach is the acetylated derivatives of claims 8-9, nor methods of using the beta-derivatives as instantly claimed.

Kawada et al. teach that saccharides are protected with acetyl groups at the 2', 3', 4', and 6' positions (see column 2, lines 62-66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to protect the saccharide with the acetyl groups. The use of acetyl groups as protecting agents in saccharide chemistry is very well known. One of skill in the art would have been motivated to

protect the compound with the acetyl groups in methods of making the products, as these protecting groups are well known in the art, and commonly used in the art. One of skill in the art would have a reasonable expectation of success in using acetyl groups as protecting agents for the saccharide synthesis, as these are well known agents in the art. Moreover, Sakai et al. teach methods of making their compounds using L-ascorbic acid and their α-glucosyl saccharide and a saccharide-transferring enzyme. As such, it would be obvious to make the β-derivatives as instantly claimed with the methods of making the α-glucosyl derivatives in the art merely by using a β-derivative as a starting compound instead of the art taught α-glucosyl compound, as well as using a β-transferase. Moreover, the fact that applicants obtained compositions comprising both 2-O and 6-O derivatives is seen to be inherent within the methods taught. That is, since the methods claimed are seen to be obvious, and the 6-O derivative is produced by the obvious method, the method of making the mixture, as well as the mixture, is also seen to be obvious. It is noted that the Sakai et al. reference discloses the alpha-derivative; however, a composition (composition plus carrier) is allowable only if no utility is disclosed for the old compound and Sakai teach that their compounds are vitamin C derivatives. See ***Ex parte Erdmann, 194 USPQ 96.*** or ***Ex parte Douros, 163 USPQ 667 (PTO Bd. App. 1968).***

Applicant's arguments filed 5/25/2007 have been fully considered but they are not persuasive. Applicants argue that Sakai does not disclose the beta compound of claim 1. However, as set forth supra, the beta derivative is seen to be disclosed in column 3, line 23. Applicants then argue the secondary reference, Kawada, fails to remedy the lack of a teaching of a beta form. However, the beta form is disclosed in Sakai, as such, is not needed to be taught or suggested by Kawada. Applicants then argue unexpected results regarding the compound.

However, it is noted that unexpected results cannot overcome a rejection which has been rejected over 102, as set forth above. Applicants then state that the Muto et al. reference provided illustrates failure in obtaining beta ascorbic acid. However, it is noted that the Muto reference uses an alpha enzyme, wherein upon making the beta forms one would not use the alpha enzyme, but rather the beta form of the enzyme, which is rejected as being obvious in light of the disclosure of the beta form of the compound in Sakai. Applicants additionally argue that the protecting groups taught by Kawada would not curb the defects of the beta forms as taught by Sakai. However, this is not found convincing, as one skilled in the art would certainly understand these are art recognized protecting groups, and it would be obvious to use these protecting groups upon the making of the beta form as disclosed in Sakai et al. Moreover, it is noted that the KSR decision forecloses the decision that teaching/suggestion/motivation is required in making an obviousness rejection.

Conclusion

Claims 13, 28, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
August 16, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623

8/20/07